

**Subpart B—Reports and Records****§ 804.25 Reports by distributors.**

(a)(1) A distributor, other than an importer, shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury.

(2) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b)(1) A distributor, other than an importer, shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

(2) An importer shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but

not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

[58 FR 46519, Sept. 1, 1993, as amended at 61 FR 44615, Aug. 28, 1996]

**§ 804.27 Where to submit a report.**

(a) Any telephone report required under this part shall be provided to 301-427-7500.

(b) Any facsimile report required under this part shall be provided to 301-881-6670.

(c) Any written report or additional information required under this part shall be submitted to:

Food and Drug Administration,  
Center for Devices and Radiological  
Health,  
Distributor Report,  
P.O. Box 3002,  
Rockville, MD 20847-3002.

**§ 804.28 Reporting form.**

(a) Each distributor that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the distributor, and submit it to FDA, and to the manufacturer as required by § 804.25.

(b) Each distributor shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to the distributor (e.g., lay user

owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the event occurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to

the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

#### **§ 804.30 Annual certification.**

(a) All distributors required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site),